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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: FUSAO, et al

Serial No.: 09/901,884

Filed: July 9, 2001

For: *CORYNEBACTERIUM AMMONIAGENES* F_0F_1-ATPASE POLYPEPTIDE [as amended]

Group: 1652

Examiner: D. Steadman

DECLARATION OF FUSAO TOMITA AND ATSUSHI YOKOTA UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Fusao Tomita and Atsushi Yokota, hereby declare as follows:

1. We are the named inventors of the above-identified U.S. Patent Application Serial No. 09/901,884, filed July 9, 2001 and of the priority application, Japanese application 2000-234317, filed August 2, 2000.

2. We, along with Hironobu Sekine and Atsuko Ishiguro, are the co-authors of the publication entitled "Cloning and analysis of the *atp* gene coding for H^+-ATPase in *Corynebacterium ammoniagenes*", the abstract of which was published in Abstracts of the Annual Meeting of the Society for Bioscience and Bioengineering,

page 80, Japan, 2000.

3. We unequivocally declare (a) that we conceived and invented the subject matter disclosed in the above-identified patent application, (b) that the abstract of the paper entitled "Cloning and analysis of the *atp* gene coding for H^+-ATPase in *Corynebacterium ammoniagenes*" describes our own work and (c) that the remaining co-authors, Hironobu Sekine and Atsuko Ishiguro, were working under our direction with respect to subject matter described in the above-identified abstract and disclosed in the above-identified patent application.

4. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Fusao Tomita Date: May 17, 2003

Atsushi Yokota Date: May 14, 2003

Example 14: Product by Function

Specification: The specification exemplifies a protein isolated from liver that catalyzes the reaction of A → B. The isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

Claim:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A → B.

Analysis:

A review of the full content of the specification indicates that a protein having SEQ ID NO: 3 or variants having 95% identity to SEQ ID NO: 3 and having catalytic activity are essential to the operation of the claimed invention. The procedures for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO: 3 which have 95% identity to SEQ ID NO: 3 and retain its activity are conventional in the art.

A review of the claim indicates that variants of SEQ ID NO: 3 include but are not limited to those variants of SEQ ID NO: 3 with substitutions, deletions, insertions and additions; but all variants must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO: 3. Additionally, the claim is drawn to a protein which **comprises** SEQ ID NO: 3 or a variant thereof that has 95% identity to SEQ ID NO: 3. In other words, the protein claimed may be larger than SEQ ID NO: 3 or its variant with 95% identity to SEQ ID NO: 3. It should be noted that "having" is open language, equivalent to "comprising".

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3.

A search of the prior art indicates that SEQ ID NO: 3 is novel and unobvious.

There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that

applicant was in possession of the necessary common attributes possessed by the members of the genus.

Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.